

**Meeting of the
PDL Implementation Advisory Committee
600 East Broad Street, Suite 1300
Richmond, Virginia
June 22, 2004**

DRAFT Minutes

Present:

Cindi Jones, DMAS, Chair
James Evans, DMHMRSAS
Sheryl Garland, Virginia Hospital & Healthcare Association
Jill Hanken, Virginia Poverty Law Center
Hill Hopper, R.Ph., Virginia Health Care Association
Mike Jurgenson, Medical Society of Virginia
Anne Leigh Kerr, PhRMA
John Pezzoli, Virginia Association of Community Services Boards
Matthew Sheffield, Boehringer-Ingelheim
Becky Snead, Virginia Pharmacy Congress

DMAS Staff:

Cheryl Roberts
Bryan Tomlinson
Wayne Turnage
Adrienne Fegans
Javier Menendez
Kelly Gent
Craig Markva
Maryanne Paccione
Katina Goodwyn

Guests: 20 guests attended

Absent:

Valeria D. Thomas, Virginia Health Care Association
Susan Umidi, Virginia League of Social Services Executives
Madeline Abbitt, Generic Manufacturers Association
David Markowitz Psychiatric Society of Virginia

FHSC Staff:

Donna Johnson
Carol Perkins

Call to Order and Review of Minutes

Cynthia B. Jones, Chief Deputy Director of the Department of Medical Assistance Services (DMAS), introduced herself as Chair, and called the meeting to order. The agenda for the meeting was reviewed. She asked the members to introduce themselves. Ms. Jones asked if there were any comments on the minutes of the March 16, 2004 meeting. No changes were noted by the Committee.

Update on General Assembly Activities

Ms. Jones provided the members with information on final budget language from the General Assembly that impact pharmacy activities. Item 326 #14c defers the inclusion of antidepressants and antianxiety medications used for the treatment of mental illness from the PDL program until July 1, 2005, pending completion of a report on the impact of including these drug classes in the PDL program. This report with the results of the review is due to the Governor, Chairman of the House Appropriations and Senate Finance Committees and the Joint Commission on Health Care by January 1, 2005. Ms. Jones advised that the P&T Committee would review antidepressants and antianxiety drug classes in September to determine if this class should be included in the PDL program. The results of this review will be shared with the Committee during its October meeting and input may be offered at that time. Item 326 #2c sets forth criteria for the Department's use in developing a new methodology for reimbursing generic drugs, referred to as Maximum Allowable Cost (MAC) program. The request for proposal to select a vendor for the MAC program has been posted.

Questions:

Matthew Sheffield asked what would be discussed regarding antidepressants and antianxiety medications at the September P&T Committee meeting since implementation is not expected until July 2005.

- The P&T Committee will review clinical information on antidepressant and antianxiety medications and discuss issues, which need to be addressed to respond to the General Assembly. The meeting will also include presentations and information from manufacturers, advocates, consumers and any other parties interested in this topic. The meeting will be held on September 20th.

Status of the PDL Program (See presentation attached)

Cheryl Roberts, Deputy Director of Programs and Operations, thanked members of the Committee for their support and work between meetings. Ms. Roberts presented pharmacy-related initiatives that have occurred since the previous Committee meeting and those that will occur before the next meeting. Ms. Roberts provided updates on PDL phases II and III, COX II clinical edit, annual review process and the MAC program.

Ms. Roberts noted P&T Committee meeting dates, August 23rd for the Phase I PDL Annual Review and September 20th for discussion of SSRIs. Ms. Roberts thanked Carol Perkins of First Health Services Corporation for her work and support on the PDL program as she transitions from the project.

Questions:

Ann Leigh Kerr clarified if long acting narcotics would be not phased in until fall.

- Correct, the long acting narcotics class will not be phased in until the fall. One issue was to establish a 72-hour policy for schedule II substance. Becky Snead was helpful with this effort. Appropriate provider notification and other administrative tasks completed for other PDL classes will be done for long acting narcotics as well.

Matthew Sheffield noted his concern with potential confusion if grandfathered recipients switch to appropriate drug therapy (NSAIDs) before it is necessary. He wants to ensure that providers and prescribers understand the new step therapy criteria and grandfathering of recipients. He says this type of program is unfamiliar to prescribers and providers in the Medicaid environment.

- Information will be sent to prescribers and providers 90 days prior to end of the effective grandfathering. At this time, prescribers may switch the recipient to appropriate drug regimen or request another prior authorization. In addition, some of the recipients will no longer be using the COXII due to an acute versus chronic condition, e.g., injury.
- Most states that use step therapy do not offer a grandfathering provision and require recipients to change their drug regimen immediately. The P&T Committee is allowing up to 18 months before a regimen must be addressed.

- The Department will offer regional training for prescribers and providers that will include updates on all recent pharmacy initiatives including the COX II clinical edit.

Jill Hanken asked how the COX II clinical edit would affect recipients who have been taking a COX II for multiple years.

- Prescribers will be able to get prior authorization for those patients with chronic conditions that need to remain on a COX II.

Ann Leigh Kerr asked if prescribers would be able to proactively request a prior authorization if recipients have unsuccessfully attempted step therapy in the past.

- Prescribers will be able to proactively request prior authorizations if deemed necessary, based on clinical information and previously attempted drug regimen.

Matthew Sheffield asked if the step therapy prior authorization criteria have been developed and how has it been made publicly available.

- The step therapy prior authorization criteria was included in the Medicaid Memo and posted to the Department's web site. This applies to those recipients with a new script for COX II.

Matthew Sheffield asked for clarification of the new drug review policy for existing PDL classes.

- The PDL new drug policy applies to drugs in therapeutic classes currently subject to the PDL, rather than all new drugs. Only drugs on the PDL will be reviewed. For combination drugs, if at least one drug is subject to the PDL, it will be reviewed.

Matthew Sheffield asked how providers would receive information on recent pharmacy initiatives if they could not attend the planned regional training sessions.

- Writings will be distributed and the Department will attempt to tape the sessions. The Department has not determined exactly how the regional meetings will operate. The Department hopes to work closely with the Health Department is scheduling these meetings.

Jill Hanken asked if the mandatory generic substitution has been operational. She asked if the Department has missed potential savings as this program has not been enforced by hard edit.

- To date, the mandatory generic substitution requirement has been a soft edit, messaging only, at the point-of-sale.
- Several initiatives to revamp the point-of-sale system have been addressed over the past year.
- There were active audits of the edit and the Department did recoup some funds in cases where the provider did not dispense generics appropriately. In addition, the Department does have a strong generic percentage utilization rate compared to other states.

- Becky Snead added that with or without the hard edit, pharmacy providers have a contractual obligation to fill scripts with generics when appropriate for Medicaid and other third party payers. She would like to speak later about possible initiatives to educate the prescriber community on mandatory generics.

Matthew Sheffield asked if bio- drugs are included in the annual review if they are in a class subject to the PDL.

- This question should be addressed by the P&T Committee, and they will address each of these drugs as they arise.

Jill Hanken asked if there was a cost savings attached to the MAC proposal.

- Yes, the cost savings estimate for the MAC program is \$10 million in total funds.

Update on the Evaluation of the PDL Program (See presentation attached)

Wayne Turnage, Director for the Division Policy and Research, provided a presentation and handouts on the evaluation of Virginia's preferred drug list: second quarter interim report. The handout will be available on the Department's web site. Mr. Turnage recognized Kelly Gent, Budget staff, the Pharmacy staff, and First Health Services' staff for their assistance with the report. The report is cumulative based on first and second quarter results.

The presentation included components of evaluation, movement of prescriptions through the PDL process, the prior authorization process, preliminary budget savings, the study report schedule, and conclusions of study results. The study conclusions include:

- Study results of the early implementation of PDL in Virginia continue to be favorable:
 - PDL compliance rate is high and most changes are being made voluntarily
 - Patients are not being denied drugs
 - The Call Center is working well
 - Early findings on market shift and comparisons of actual pharmacy spending to forecasted expenditures suggest the program is saving the Commonwealth money
- More conclusive findings on the impact of PDL on pharmacy savings will be developed later this year.

Questions:

Ann Leigh Kerr asked for clarification of how the First and Second phases noted in the presentation relates to the phase-in schedule of the PDL implementation.

- Phases noted in the presentation represent the statistical analysis not the PDL implementation phase-in schedule. The first and second phases of analysis include phase one of PDL program implementation.

Ann Leigh Kerr asked if we could determine which of these therapeutic classes have more drugs available and coverage of drug to determine the affect on compliance.

- In the first report, the impact of the coverage rate of each drug class on the compliance rate was evaluated. No evidence was found that drug classes with only a small percentage of drugs on the PDL affected the compliance rate. No additional research was conducted. Overall the compliance rates are very high; therefore there will be few differences in variables. Mr. Turnage will review to determine the potential affect of coverage.

Sheryl Garland asked if data is available for trends by prescriber, provider and/or region that may be used for educational purposes.

- Reporting at the provider or regional level has not been conducted. There has been a high overall compliance rate; therefore, no issues have been identified that require further research. At this point, whatever variable is controlled will produce similar results. Compliance will be monitored and reporting will provided at prescriber, provider and/or regional level, as necessary if the compliance rate begins to fall.

Matthew Sheffield noted that, based on data shown in slide 8 of the presentation, the analysis does not account for nearly half of the preferred drugs; therefore, how realistic is the other data provided, e.g., compliance rate (slide 14). He states that one-year's data would be warranted to accurately reflect compliance.

- Those claims that have not been accounted for are not included in the compliance rate. Mr. Turnage states that data analysis will continue and statistical tests were conducted to evaluate these sample data. Some claims have not been submitted and as they become available it will enhance the analysis.
- Jill Hanken added that claims that are not found are no longer an issue as the drug regimen may have been changed or discontinued. These prior claims will not be considered with the compliance rate.

Jill Hanken asked for clarification of the 1% denials noted on slide 9 compared to no denials noted since program implementation on slide 16.

- Slide 9 reflects denials that may be unrelated to the PDL process, i.e., eligibility, etc.

Ann Leigh Kerr stated that PDL savings of \$8 million was noted during a recent JLARC meeting presentation.

- Cindi Jones clarified that she provided a savings estimate of \$8-\$9 million based on supplemental rebates only, not claim-specific changes in drug therapy as noted in the cost savings analysis.

Matthew Sheffield asked for information on the outcome of First Health's savings analysis.

- First Health provided two estimates: 1) savings based on regression model of approximately \$2.5 million in savings and 2) saving based on an alternative model that

was only \$500,000. The second model could not be accurate based on the market shift alone.

Jill Hanken asked if supplemental rebates are paid as drugs are dispensed.

- No, supplemental rebate invoices are sent to manufacturers at the end of each quarter following the drug claims. The invoices are based on the drug utilization and rebate percentage of unit costs. The manufacturer has 45 days after the invoice is received to either pay the supplemental rebate or dispute the calculated amount of the invoice. This process may affect the savings estimates going forward.

Matthew Sheffield asked when First Health would provide a final cost savings estimate.

- Mr. Turnage stated that he was not sure of the date but would investigate.

Jill Hanken asked if the emergency 72-hour requests are being tracked.

- Yes, these figures are tracked in the weekly call center activity data. Katina Goodwyn provided the total of 210 in the prior week when there was a total of approximately 900 PAs. Javier Menendez added the majority of the 72-hour requests are from long-term care facilities and that the total could not be correlated to the number of PAs during a specific week. Mr. Menendez added that there are approximately 2,000 drug claims per week, of which emergency requests are a small percentage.

Hill Hopper asked if the Department anticipated any provider concerns or confusion related to the PDL implementation of antibiotic classes and what efforts are being taken to make providers aware. He recommended a second mailing related to antibiotics due to the sensitivity of these agents.

- The Department noted that the Medicaid Memo related to this class was just released. Cheryl Roberts offered to distribute a postcard prior to the implementation of hard edits for antibiotics.
- Becky Snead noted that 72-hour requests for antibiotics may escalate; however she does not anticipate any major issues.

Hill Hopper asked if IV drugs are subject to the PDL.

- Most IV products are not distributed at point-of-sale; however, they would be subject to the PDL if purchased at point-of-sale.

Jill Hanken asked if a 72-hour request is ever made when there is not a pending prior authorization request. She would like to know more about how the 72-hour requests are working, especially with non-institutionalized recipients.

- Yes, it is possible to submit a 72-hour request without finalizing with a prior authorization. The Department will determine the appropriate method of analyzing the 72-hour requests and information will be included with the next program evaluation.
- Carol Perkins added that if a 72-hour request is made and the criteria for prior authorization are met at that time, the prior authorization will be provided.

Technology Update (See presentation attached)

Bryan Tomlinson, Director of DMAS Health Care Services Division, provided a presentation of upcoming PDL-related technology initiatives. The goal is to streamline and expedite the use of the PDL for providers and prescribers. These initiatives include the ePocrates personal data assistant (PDA) software for access to the preferred drug list (PDL) and the web-based PDL prior authorization system. The Virginia Medicaid- specific ePocrates software will be made available to prescribers and providers in September 2004. The implementation date for the web based PA system has not been determined but most likely in September or October 2004. Prior to implementation of the web based PA, the system will be beta tested with various prescribers in multiple practice settings throughout the state. The web based PA is new technology for First Health Services and is currently being piloted in the state of Michigan.

Questions:

Matthew Sheffield asked if both systems would have the prior authorization or step therapy criteria available.

- The web based PA system will have the criteria and step therapy set for each drug. Also, the Department will be able to customize the ePocrates software to include the criteria as well.

Ann Leigh Kerr inquired about the alternative drug listing available via the web based PA system.

- The alternative drug list is available for each drug class and/or diagnosis. When a non-preferred drug is selected, optional preferred drugs within the drug class will appear.

Ann Leigh Kerr requested a copy of the web based PA design being used in Michigan.

- Carol Perkins stated that she could provide a copy of the users guide within the next couple of weeks.

Matthew Sheffield asked how the web based system protects against errors, e.g, drug names, diagnosis, etc.

- Carol Perkins stated the web based system could provide correct drug names and diagnoses with a partial description. In addition, the system will verify with the user multiple times that they entered the information as intended.

Hill Hopper asked about the turnaround time for an approval of a PA submitted via the web.

- The web PAs will be reviewed and approved within 24-hours similar to PAs received via fax.

ProDUR Program Update (See presentation attached)

Javier Menendez, DMAS Pharmacy Manager, provided a presentation on updates to the Prospective Drug Utilization Review (ProDUR) program. The presentation included background of the ProDUR program, DUR Board initiatives and recent ProDUR enhancements.

Questions:

Jill Hanken asked if ProDUR includes the threshold program.

- No, threshold is a separate initiative and the Department will provide information on the threshold program at the next meeting. Some issues related to inappropriate high drug utilization are addressed through ProDUR programs.

Other Issues

No other issues were addressed.

Schedule Next Meeting

Cheryl Roberts stated that at the next meeting the Committee would receive information on the results of the P&T Committee's annual review and SSRI discussions, the Maximum Allowable Costs (MAC) program, and the Threshold program. Becky Snead requested an update of PDL savings at the next meeting. Wayne Turnage will provide an update on savings with the third quarter PDL evaluation. Becky Snead also requested information on the mandatory generic edit at the next meeting.

The next meeting has been tentatively scheduled for October 12, 2004.

Adjournment

There being no further business, the meeting was adjourned.